## NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

**3401. ACTH. U. S. v. 1 Jar, etc.** (F. D. C. No. 29802. Sample No. 73760–K.)

LIBEL FILED: October 19, 1950, Southern District of New York.

ALLEGED SHIPMENT: On or about September 14, 1950, by the Princeton Laboratory Products Co., from Princeton, N. J.

PRODUCT: 1 jar containing 25.3 grams and 1 jar containing 21.6 grams of *ACTH*, together with 2 1-gram vials, 1 500-microgram vial, and 12 100-microgram vials of the same product at New York, N. Y.

LABEL, IN PART: "Biological Derivatives, Inc. * * * ACTH (Princeton)."

NATURE OF CHARGE: Section 505 (a), the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to such drug.

DISPOSITION: January 24, 1951. Default decree of condemnation. The court ordered that the product be delivered to the Food and Drug Administration, to be used for experimental purposes.

## DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

**3402. Misbranding of Tuinal capsules and phenobarbital tablets. U. S. v. Bradley's Drug Store, Inc. Plea of guilty. Fine, $800** (F. D. C. No. 29461. Sample Nos. 2354–K to 2358–K, incl., 3005–K to 3008–K, incl.)

INFORMATION FILED: October 30, 1950, Western District of Virginia, against Bradley's Drug Store, Inc., Bristol, Va.

INTERSTATE SHIPMENT: From the States of Indiana and Maryland into the State of Virginia, of quantities of *Tuinal capsules* and *phenobarbital tablets*.

ALLEGED VIOLATION: On or about August 9, 10, 12, 13, 15, 16, 19, 20, and 22, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and sold without a prescription, which acts of the defendant resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs bore no label containing a statement of the quantity of the contents.

Further misbranding, Section 502 (d), the drugs contained derivatives of barbituric acid, which derivatives had been found to be, and by regulations designated as, habit forming; and the repackaged drugs failed to bear labels containing the names, and quantity or proportion of such derivatives and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use in that the directions, namely, "One capsule at bedtime as needed for rest" and "Tabs one at bedtime if needed for rest," borne on the labeling of the repackaged drugs, were not adequate directions for use.

DISPOSITION: April 11, 1951. A plea of guilty having been entered, the court imposed a fine of $800 against the defendant.

**3403. Misbranding of phenobarbital tablets and Dexedrine Sulfate tablets. U. S. v. Smith's of Spartanburg, Inc., and Richard B. Burnett. Pleas of nolo contendere. Fine of $100 against corporation and $25 against**